UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,667	08/26/2003	Chengjin M. Huang	AM101193	3920

25291 7590 03/10/2005

WYETH
PATENT LAW GROUP
5 GIRALDA FARMS
MADISON, NJ 07940

EXAMINER	
LE, EMILY M	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/648,667	HUANG, CHENGJIN M.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2003 and 22 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *11-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 19-22* is/are rejected.

7)☒ Claim(s) *1-10 and 19-21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/26/03 + 1/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-10 and 19-22 in the reply filed on 12/22/04 is acknowledged. The traversal is on the ground(s) that

i) the evidence and explanation fail to establish a serious burden,

ii) the scope of the search for the elected invention will necessarily cut across all the classes described in the restriction

Applicant's submission items i)-ii) have been considered, however, it is not found persuasive because Applicant has not provided distinctly and specifically points out the supposed errors in the examiner's action.

iii) in one specific aspect, the explanation in the restriction as to why the invention of Groups I and V (claims 15-18) are distinct is not understood.

Applicant's submission has been considered, however, it is not found persuasive. It is unclear why Applicant does not understand the explanation provided within the office action. In accordance with MPEP § 806.05(f), inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)), wherein the distinction provided in the analysis need not be limited to Applicant's invention.

Additionally, Applicant is reminded that if the claimed product is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the

limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

The requirement is still deemed proper and is therefore made FINAL.

Status of Claims

2. Claims 1-22 are pending. Claims 11-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/22/04. Claims 1-10 and 19-22 are under examination.

Claim Objections

3. Claims 1-10 and 19-21 are objected to because of the following informalities: the use of abbreviation should be avoided in the claims. However, if it is necessary to use abbreviation for brevity purpose, the abbreviation should be spelled out in the first instance of use in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-10 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are directed to an antibody having a specific binding characteristic; however, it is unclear as to the epitope in which the claimed antibody is required to bind. The claims recite "an epitope unique to an inactivated FIV-encoded glycoprotein". However, it is unclear from such recitation what is encompassed by "unique epitope" in which the claimed antibody binds. No additional insight as to what is encompassed by "unique epitope" can be rendered from the disclosure. The specification only provides a broad definition for the term "epitope", which is a specific amino acid sequence that is recognized by the antibody.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 6-7 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel biological materials, specifically monoclonal antibody 1D9 and cell line deposited as ATCC number PTA-4837. Since the biological materials are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 U.S.C § 112 may be satisfied by a deposit of biological materials. The specification

does not disclose a repeatable process to obtain the biological materials and it is not apparent if the biological materials are readily available to the public. Applicant may make a deposit at an acceptable depository, which 37 CFR 1.803 provides as

(a) A deposit shall be recognized for the purposes of these regulations if made in:

(1) any International Depositary Authority (IDA) as established under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, or

(2) any other depository recognized to be suitable by the Office.

If the deposit is not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney or record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last requires or from the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of the deposit will be made (see 37 C.F.R. § 1.807); and

(e) the deposit will be replace if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. § 2400 in general, and specifically to § 2411.05, as well as to 37 C.F.R § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information, however Applicant is cautioned to avoid the entry of new matter into the specification by addition any other information. Finally, Applicant is advised that the address of the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection

10801 University Boulevard

Manassas, VA 20110-2209

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-8, 10 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al., U.S Patent No. 5275813.

a. The following analysis is for claims 1-2, 4-6 and 10: The claims are directed to a monoclonal antibody that binds to an inactivated FIV-encoded glycoprotein. Claim 2 limits the glycoprotein to that of FIV-Petaluma. Claim 10 requires the virus be

inactivated by treatment with formalin. Claim 4 requires that the claimed antibody be produced from a hybridoma cell line via a specific process. Additionally, claim 5, which depends on claim 4, requires that the cell line in which the claimed antibody is obtained be suitable for obtaining a monoclonal antibody specific for an epitope unique to an inactivated FIV-encoded glycoprotein selected from gp95 and gp130. Claim 6, which also depends on claim 4, requires that the claimed monoclonal antibody be produced from the cell line deposited as ATCC number PTO-4837.

It is noted that claims (claims 4-6) contain limitation(s) regarding the process in which the claimed antibody is made; Applicant is reminded that patentability of a product-by-process claim is determined based on the product itself, not on the process of making it. See In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985), and MPEP § 2113.

In the instant, Yamamoto et al. teaches a monoclonal antibody that binds to an inactivated FIV-encoded glycoprotein. [Lines 58-68 of column 3 to lines 1-63 of column 4.] FIV isolates Yamamoto et al. teaches includes FIV-Petaluma. [Lines 23-39 of column 13.] The viral isolates Yamamoto et al. teaches are inactivated by treatment with formalin. [Lines 24-36 of column 11.] Yamamoto et al. anticipates the limitation(s) recited in claims 1-2, 4-6 and 10.

b. The following analysis is for claims 3 and 8: The claims limit the inactivated FIV-encoded glycoprotein to gp95.

Even though Yamamoto et al. does not literally teach a monoclonal antibody that binds to inactivated FIV-encoded gp95; Yamamoto et al. does teach an antibody that

binds to inactivated FIV-encoded glycoprotein. The inactivated FIV-encoded glycoprotein in which the antibody of Yamamoto et al. binds have an approximate molecular weight of 100 kilo Daltons. [Figure 5A] Applicant discloses that the claimed antibody binds to an inactivated FIV-encoded glycoprotein, the SU subunit of the glycoprotein; wherein the SU subunit have an approximate molecular weight of 95 to 100 kilo Daltons. The antibody of Yamamoto et al. is the same as that of the claimed invention, in view of the commonalities shared between the antibody disclosed by Applicant and the antibody Yamamoto et al. teaches. Ergo, Yamamoto et al. anticipates the limitation(s) recited in claims 3 and 8.

c. The following analysis is for claim 7: The claim limits the antibody that binds to inactivated FIV-encoded glycoprotein to mAb 1D9.

Although the antibody that Yamamoto et al. teaches is not defined as mAb 1D9, Yamamoto et al. teaches an antibody that binds to inactivated FIV-encoded glycoprotein, wherein the approximate molecular weight of the glycoprotein is 100 kilo Daltons. [Figure 5A] Applicant discloses that mAb 1D9 binds to an inactivated FIV-encoded glycoprotein, the Su submit of the glycoprotein; wherein the subunit has an approximate molecular weight of 95 to 100 kilo Daltons. The antibody of Yamamoto et al. is the same as that of the claimed invention in view of the commonalities shared between the antibody disclosed by Applicant and the antibody Yamamoto et al. teaches. Ergo, Yamamoto et al. anticipates the limitation(s) recited in claim 7.

d. The following analysis is for claims 19-21: Claim 19 is directed at a hybridoma cell line that is suitable for obtaining an antibody that binds to an inactivated FIV-

encoded glycoprotein. Claim 20 requires that the hybridoma cell line be suitable for obtaining an antibody that binds to an inactivated FIV-encoded glycoprotein, specifically an antibody that binds to inactivated FIV-encoded glycoprotein, wherein the glycoprotein is gp95 or gp130. Claim 21 requires that the cell line be used to obtain mAb1D9.

It is noted that claim 19 additionally contains limitation(s) regarding the process in which the claimed hybridoma cell line is made; Applicant is reminded that patentability of a product-by-process claim is determined based on the product itself, not on the process of making it. See In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985), and MPEP § 2113.

Yamamoto et al. also teach a hybridoma cell line. Yamamoto et al. teaches the use of the hybridoma cell line to obtain antibody. [Lines 62-68 of column 9 to lines 1-40 of column 10.] Although, Yamamoto et al. does not specifically teach the use of the hybridoma cell line to produce mAb 1D9 and antibody that binds to an inactivated FIV-encoded glycoprotein, specifically an antibody that binds to inactivated FIV-encoded glycoprotein--wherein the glycoprotein is gp95 or gp130; the hybridoma cell line of Yamamoto et al. is suitable for use in producing antibodies as claimed, particularly since Applicant has not disclosed of the particulars that the hybridoma cell line must possess to produce mAb 1D9 and antibody that binds to an inactivated FIV-encoded glycoprotein--wherein the glycoprotein is gp95 or gp130. Ergo, Yamamoto et al. anticipates the limitation(s) recited in claims 19-21.

In summation, Yamamoto et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 9 is rejected under 35 U.S.C. 103(a) as being obvious over Yamamoto et al., U.S Patent No. 5275813 in view of Kakinuma et al.

The claim requires that the inactivated FIV-encoded glycoprotein to be that of FIV-Shiz.

The teaching of Yamamoto is noted above. Yamamoto et al. does not teach an antibody that binds to inactivated FIV-Shiz encoded glycoprotein. Yamamoto et al. suggests that other FIV isolates can be used with the teaching of provided. Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use any inactivated FIV isolate. One of ordinary skill in the art would have a reasonable expectation of success for doing using any FIV isolate to induce antibodies that bind to the inactivated FIV-encoded glycoprotein because Yamamoto et al. teaches an antibody that binds to inactivated FIV-encoded glycoprotein; and the protein structure of the glycoprotein among FIV isolates have significant homology to one another, as evidenced by Kakinuma et al. Kakinuma et al. teaches that envelope glycoprotein across a multitude of different FIV-isolates have significant structural similarity to one another.

Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey S. Parkin, Ph.D.
Primary Patent Examiner
Art Unit 1648

E.Le